

# In the United States Court of Federal Claims

No. 06-371V

(Filed: December 4, 2014)

(Reissued: December 19, 2014)

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<b>FRANCIA HIRMIZ and PETER HIRMIZ,</b>	)	Vaccine case; administration of half-
<b>as best friends of their daughter, J.H.,</b>	)	doses of influenza vaccine to a child;
	)	causation related to neurological
<b>Petitioners,</b>	)	degeneration; pre-existing condition
	)	
<b>v.</b>	)	
	)	
<b>SECRETARY OF HEALTH AND</b>	)	
<b>HUMAN SERVICES,</b>	)	
	)	
<b>Defendant.</b>	)	
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John F. McHugh, New York, NY, for petitioner.

Linda S. Renzi, Senior Trial Counsel, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for defendant. With her on the briefs were Joyce R. Branda, Acting Assistant Attorney General, Civil Division, Rupa Bhattacharyya, Director, Torts Branch, Civil Division, Vincent J. Matanoski, Deputy Director, Torts Branch, Civil Division, and Gabrielle M. Fielding, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

## OPINION AND ORDER

LETTOW, Judge.

Petitioners, Francia and Peter Hirmiz, on behalf of their daughter, J.H., seek review of a decision by a special master dated August 26, 2014, denying them an award under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3755 (1986) (codified, as amended, at 42 U.S.C. §§ 300aa-1 to -34) (“Vaccine Act”). Petitioners allege that the injection of their daughter with two half-doses of influenza vaccine, administered on October 14, 2004 and November 16, 2004, caused her subsequent severe neurological degeneration. The Secretary of Health and Human Services (“the government”) acknowledges J.H.’s compromised condition but argues that its cause is unrelated to inoculation of the vaccine.

J.H. to date has no confirmed diagnosis. Petitioners claim an off-Table vaccine injury for which they must establish causation in fact by a preponderance of the evidence. *See* 42 U.S.C. §§ 300aa-11(c)(1)(B), (C)(ii)(I); 300aa-13(a)(1); *Althen v. Secretary of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The special master, applying the test set forth in *Althen*, denied relief on the ground that petitioners “failed to demonstrate that it is ‘more probable than not’ that this pair of vaccinations contributed to causing their daughter’s condition.” *Hirmiz v. Secretary of Health & Human Servs.*, No. 06-371V, slip op. at 7 (Fed. Cl. Spec. Mstr. Aug. 26, 2014) (“Entitlement Decision”).<sup>1</sup> The special master additionally noted that “it appears more likely than not that J.H.’s condition predated these vaccinations.” *Id.* Petitioners challenge the special master’s decision, maintaining that their theory of an autoimmune attack on the nervous system triggered by the vaccinations is “plausible, probable[,] and entirely consistent with the facts,” claiming that the special master “arbitrarily ignored the great weight of the evidence,” and averring that his conclusion was “contrary to law.” Pet’rs’ Pet. for Review of the Decision of the Office of Special Mstrs. dated Aug. 26, 2014 (“Pet’rs’ Mot.”) at 1, 16, 18, ECF No. 121.<sup>2</sup> The petitioners’ motion for review has been fully briefed and a hearing was held on November 13, 2014.

### STATEMENT OF FACTS

J.H. and her twin brother were born on January 12, 2004. Entitlement Decision at 5. During the first few months of her life, J.H.’s development appeared normal. *Id.* She had well-child exams at the ages of sixteen days and six months and received vaccinations for DTaP, HIB, Hep B, and Prevnar on March 15, May 17, and July 16, 2004. *Id.* No concerns or adverse reactions to any immunizations were recorded. *Id.* The pediatrician’s checklist for the pediatric visit held on July 16, 2004 indicated that J.H. was capable of rolling over in both directions and “sits with support/alone.” *Id.* (quoting Ex. 4 at 25, Ex. 10 at 7).<sup>3</sup>

The first mention in the record of J.H.’s developmental delays was generated on October 14, 2004. On that date, a medical note chronicling J.H.’s pediatric visit stated that J.H. was not rolling over and not sitting alone, indicating a loss of some skills between July and October

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<sup>1</sup>The Entitlement Decision was rendered by a special master who had been assigned to the case after the originally assigned special master had retired.

<sup>2</sup>In their motion, petitioners state that J.H. suffered “an obvious aggravation of any prior condition.” Pet’rs’ Mot. at 1. Nonetheless, until the hearing held on the motion for review, petitioners had not raised a significant-aggravation claim before the special masters. Such a claim would require analysis under the six-part test outlined in *Loving ex rel. Loving v. Secretary of Dep’t of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009). *See W.C. v. Secretary of Dep’t of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Petitioners did move at the hearing to amend their petition for compensation to state such a claim. Hr’g Tr. 52:11-18 (Nov. 13, 2014). The court will address a putative significant-aggravation claim in the analysis that follows.

<sup>3</sup>The exhibits petitioners presented to the special masters are designated numerically, while the government’s exhibits are marked with letters.

2004. Entitlement Decision at 5. J.H. was also observed to have decreased muscle tone on her left extremity. *Id.*; Pet'rs' Mot. at 3. J.H. received a first half-dose of the influenza virus vaccine on that date. Entitlement Decision at 5. Petitioners testified that after the first influenza vaccination they noticed that J.H. cried continuously, no longer slept through the night, and lost her ability to support her own weight. Pet'rs' Mot. at 3. J.H. received a second half-dose on November 16, 2004, approximately one month after receiving the first half-dose. This dose was received at a pediatric visit during which she was also referred to a neurologist. *Id.* at 5.<sup>4</sup>

J.H. had a PT evaluation at Children's Memorial Hospital on December 9, 2004, at which she was found to be "developmentally delayed with her attainment of gross motor milestones" and suffered "[s]ignificantly decreased strength due to increased tone/spasticity at bilateral lower extremities . . . [,] display[ed] decreased proximal trunk strength and neck extensor muscles," and "ha[d] increased tone/spasticity throughout bilateral lower extremities." Pet'rs' Mot. at 4 (quoting Ex. 4 at 368-69). At that time, J.H. was "unable to bring hands to midline or to grab for toys." *Id.* J.H.'s first neurological evaluation was performed by Dr. David Stumpf on December 20, 2004. Entitlement Decision at 5. Dr. Stumpf observed "increased tone in her lower extremities" due to "great resistance to reach 90 degree[s] in flexion" and diagnosed J.H. with spastic diplegia and cerebral palsy, which he suggested resulted from "twinning." Pet'rs' Mot. at 5 (quoting Ex. 4 at 371); Entitlement Decision at 6. Early in 2005, J.H. suffered a marked neurological deterioration. For several months, J.H.'s mother reported that she gained no weight, a fact reflected in her weight chart, which lists J.H. in the 75th percentile at 9 months of age, in the 60th percentile at 12 months, in the 10th percentile by 15 months and only in the 5th percentile at 18 months. Pet'rs' Mot. at 4; *see also* Pet'rs' Reply to Resp't's Post Hearing Mem. at Exs. D, E, ECF No. 115. At her 12-month well-child pediatric visit on January 18, 2005, the medical records indicate that although J.H. could use single words, drink from a cup with help, and feed herself some solids, she was unable to pull to stand, walk independently, or grasp objects and was no longer lifting her head. Pet'rs' Mot. at 5; Entitlement Decision at 6. The doctor assessed J.H. to be "well developed but with muscle weakness, motor delay." Entitlement Decision at 6 (quoting Ex. 10 at 9). J.H. also began physical therapy in early 2005, which her parents reported improved her "prone activity, sitting and lower limb kicking;" her medical records, however, noted that she was not "using her bilateral extremities as functionally as she used to." *Id.* (quoting Ex. 6 at 469).

Subsequently, J.H. was evaluated extensively at Children's Memorial Hospital by a number of physicians, including neurologists, geneticists, pediatricians, orthopedic surgeons, and physical and rehabilitation specialists. Entitlement Decision at 6. In late March 2005, her parents and physical therapist noted difficulty feeding, inability to maintain a sitting position, and the onset of clenched fists. *Id.* When Dr. Stumpf reevaluated her on April 18, 2005, he observed a significant increase in spasticity and noted that additional tests were needed to determine whether J.H. had a degenerative disorder. *Id.* At her 15-month check-up on April 19, 2005, Dr. Peera assessed her with global developmental delays and "CP," *i.e.*, presumably, cerebral palsy. Pet'rs' Mot. at 6. J.H.'s swallowing function studies and MRIs with contrast of the brain and cervical cord, administered in May 2005, were deemed normal. Entitlement

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<sup>4</sup>There are no medical records for the period between the administration of the first and second halves of the influenza vaccination. Pet'rs' Mot. at 3.

Decision at 6. In June 2005, J.H.'s diagnosis of cerebral palsy was reassessed after Dr. Stumpf found her to have atypical features. *Id.* at 7. During that time, she was diagnosed with "spastic quadriplegia, etiology unclear" and was assessed at the Rehabilitation Institute of Chicago as being characterized by "very poor head control [and] trunk control." Entitlement Decision at 6 (quoting Ex. 4 at 334). Despite physical therapy, J.H.'s motor function worsened. *Id.* In November 2005, J.H. was evaluated at the Mayo Clinic where, despite extensive testing, her doctors could not agree on a diagnosis. *Id.*

In 2008, J.H. was evaluated by Mark Geier, M.D. who performed additional testing, including an entire genome microarray, but was similarly unable to offer a diagnosis. Entitlement Decision at 6. To date, J.H. has no definitive diagnosis for her neurological condition. *Id.*

### PROCEDURAL HISTORY

Mr. and Mrs. Hirmiz filed their petition for compensation on behalf of J.H. under the Vaccine Act on May 8, 2006. Their original petition alleged that "a series of vaccinations administered on March 15, 2004, May 17, 2004, [and] September 17 and 18, 2004" caused J.H. to experience "a degeneration of her motor skills and body control noticeable after mid-October of 2004." Resp't's Mem. in Resp. to Pet'rs' Mot. for Review ("Resp't's Mem.") at 4, ECF No. 123 (quoting Pet'rs' Pet. for Compensation, ECF No. 1). After the government contested that claim, petitioners altered their position regarding the onset of J.H.'s condition in an amended petition filed on March 5, 2007. Entitlement Decision at 4. Unlike the original petition, which asserted that "J.H. progressed normally for about eight months," the amended petition alleged that J.H. progressed normally "for about over ten months, *i.e.*, at least until October 14, 2004" and asserted that J.H.'s failure to progress resulted from the half-dose influenza vaccines administered on October 14, 2004 and November 16, 2004. Pet'rs' Am. Pet. (filed with the court in paper form) at 1.

On August 28, 2008, an "onset hearing" was held before the originally assigned special master, at which petitioners testified about the onset of J.H.'s condition. Entitlement Decision at 4; Transcript of Proceedings, Aug. 28, 2008 ("2008 Tr."), ECF No. 37 (submitted to the court in paper form). On January 14, 2010, the special master issued a bench ruling, finding that the onset of J.H.'s symptoms occurred between July 16, 2004 and October 14, 2004, before the administration of J.H.'s influenza vaccinations:

[T]here is some form of regression which has been initiated prior to the 14th of October. It seems to deteriorate, or accelerate, rapidly between October 14 and November, whatever the date was, perhaps the 16th, yes, and thereafter. In fact, the records are replete with that acceleration of degeneration of whatever the problem is.

Transcript of Proceedings, Jan. 14, 2010 ("2010 Tr."), at 15, ECF No. 56; *see also* Hr'g Tr. 14:18 to 16:24 (Nov. 13, 2014).

Following the initially assigned special master's retirement, the case was reassigned to another special master. Entitlement Decision at 4.<sup>5</sup> After the filing of expert reports by the petitioners and the government, a second evidentiary hearing was held on December 5, 2012, to hear testimony from the parties' experts. *Id.* at 5; Transcript of Proceedings, Dec. 5, 2012 ("2012 Tr."), ECF No. 104. During that hearing, petitioner's expert, Dr. James M. Oleske, testified that J.H.'s neurological condition was likely due to the two half dosages of influenza vaccine she received at 9 and 10 months of age, which were temporally related to the onset of her worsening neurological symptoms. Entitlement Decision at 8.<sup>6</sup> Dr. Oleske asserted that a severe decline started to occur at 12 months of age, causing her growth to decrease drastically over the next three months. *Id.* at 8-9; 2012 Tr. at 20-22, 70. He suggested that J.H.'s neurological deterioration may have been due to an unusual immunological response to the flu vaccine. Entitlement Decision at 9. The government's expert, Dr. Stephen J. McGeady, disagreed and testified that there was no evidence in J.H.'s medical records that she suffered immune dysfunction in her first six months of life and emphasized that J.H. received routine immunizations early in her life without any reported adverse reactions. *Id.* at 9-10; 2012 Tr. at 77-78, 85.<sup>7</sup> Dr. McGeady opined instead that J.H. demonstrated signs of a loss of skills between July and October of 2004, before the administration of the influenza vaccinations. Entitlement Decision at 10; 2012 Tr. at 87. According to Dr. McGeady's testimony, "for an infant not to have made significant physical skill acquisition between the ages of six and nine months (July to October 2004) would have been highly abnormal, and to have *lost* skills in that time period would be alarming." Entitlement Decision at 10 (emphasis in original); 2012 Tr. at 82-83. Dr. McGeady concluded that it was more likely than not that J.H.'s rapid deterioration in late 2004 was an extension of a neurodegenerative process that began before October 14, 2004. Entitlement Decision at 10.

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<sup>5</sup>Petitioners did not thereafter request that the new special master personally hear testimony regarding the onset of J.H.'s condition. Resp't's Mem. at 5 n.5.

<sup>6</sup>Dr. Oleske is a pediatric immunologist, serving as a Professor at the School of Public Health, University of Medicine and Dentistry of New Jersey, a Clinical Professor at the New Jersey School of Nursing, and a Professor of Preventive Medicine and Pathology in the Department of Pediatrics at the University of Medicine and Dentistry of New Jersey. Ex. 16 at 3. His resume lists 212 peer-reviewed publications. *Id.* at 19-33. He is certified by the Specialty Board of the American Board of Pediatrics, Sub-Specialty Board of the American Board of Allergy/Immunology, the Sub-Specialty Board of the American Board of Pediatric and Pediatric Infectious Diseases, the American Board of Medical Laboratory Immunology, the American Board of Hospice and Palliative Care, the American Academy of Pain Management, the Council of Certification of IRB Professionals, and the American Academy of HIV Medicine. *Id.* at 2.

<sup>7</sup>Dr. McGeady serves as Director of the Allergy and Clinical Immunology Training Program at the Jefferson College of Medicine and as Chief, Allergy, Asthma, and Immunology Division, DuPont Hospital for Children. Ex. B at 1. His resume lists 54 peer-reviewed articles. *Id.* at 2-6. He is certified by the American Board of Pediatrics, the American Board of Allergy and Immunology, and the Board of Diagnostic Laboratory Immunology. *Id.* at 1.

On August 26, 2014, the successor special master issued a decision denying compensation to petitioners. Entitlement Decision at 2. The special master held that petitioners failed to prove by a preponderance of the evidence that the half doses of influenza vaccine administered to J.H. on October 14, 2004 and November 16, 2004 caused J.H.'s neurological degeneration. *Id.* at 7, 20. In so holding, the special master relied on the three-prong framework for establishing causation outlined in *Althen*, 418 F.3d 1274, requiring a petitioner to establish by preponderant evidence that the vaccination caused the injury by providing:

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury.

Entitlement Decision at 16 (quoting *Althen*, 418 F.3d at 1278).<sup>8</sup>

Regarding the first element of the *Althen* analysis, the special master observed that the petitioners failed to show “that influenza vaccinations of any kind can cause the type of injury from which J.H. suffers.” Entitlement Decision at 19 (original emphasis omitted). The special master concluded that petitioners could not establish the first prong because their reliance on “immune dysfunction” and “challenge/rechallenge” theories was insufficient to meet the burden of demonstrating a plausible medical theory. *Id.* With regard to *Althen*'s second prong, the special master noted that the petitioners did not meet their burden of establishing cause and effect because they were unable to show that J.H. suffered rapid neurological downturns after either of her influenza vaccinations. *Id.* In addition, the special master observed that petitioners were unable to establish that J.H.'s case fit either an “immune dysfunction” or a “challenge/rechallenge” scenario. *Id.* Finally, in analyzing the third prong of *Althen*, the special master concluded that petitioners failed to demonstrate a proximate temporal relationship between the influenza vaccinations and J.H.'s injury. *Id.* The special master found that petitioners' expert, Dr. Oleske, relied upon a flawed assumption of fact regarding the onset of J.H.'s neurological disorder and failed to offer any persuasive evidence as to when the first symptoms of an influenza-vaccine-caused disorder may appear. *Id.* at 19-20.

Petitioners filed a Motion for Review in this court on September 23, 2014.

### STANDARDS FOR REVIEW

Under the Vaccine Act, in reviewing a decision of a special master on a motion for review, the court may take any of the following actions:

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<sup>8</sup>The special master noted that the *Althen* analysis could be applied despite J.H.'s lack of an official diagnosis because both parties' experts agreed that J.H. suffered neurological degeneration and there is no affirmative burden on the petitioner to establish a specific diagnosis. Entitlement Decision at 17-18 (citing *Kelley v. Secretary of Health & Human Servs.*, 68 Fed. Cl. 84, 100 (2005) (“The Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury—regardless of the ultimate diagnosis.”)).

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2).

The special master's determinations of law are reviewed *de novo*, *Andreu v. Secretary of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009), and findings of fact are reviewed for clear error, *id.*; see also *Broekelschen v. Secretary of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious." (citing *Capizzano v. Secretary of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006))). In making his determination, the special master must "consider all relevant and reliable evidence." Rule 8(b)(1) of the Vaccine Rules of the United States Court of Federal Claims; see also 42 U.S.C. § 300aa-13(b)(1) ("[T]he special master or court shall consider the entire record and the cause of the injury, disability, illness, or condition until the date of the judgment of the special master or court."). A special master's findings regarding the probative value of presented evidence and the credibility of witnesses will not be disturbed so long as they are "supported by substantial evidence." *Doe v. Secretary of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitcotton v. Secretary of Health & Human Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996)); see also *Porter v. Secretary of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). Nonetheless, a deferential standard of review "is not a rubber stamp." *Porter*, 663 F.3d at 1256 (O'Malley, J., concurring in part and dissenting in part). The special master must draw plausible inferences and articulate a rational basis for his decision. *Hines ex rel. Sevier v. Secretary of the Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); see 42 U.S.C. § 300aa-13(b)(1). Although the special master need not address every individual piece of evidence presented in the case, see *Doe*, 601 F.3d at 1355; he cannot dismiss contrary evidence to the extent that it appears that he "simply failed to consider genuinely the evidentiary record before him," *Campbell v. Secretary of Health & Human Servs.*, 97 Fed. Cl. 650, 668 (2011); see also *Paluck ex rel. Paluck v. Secretary of Health & Human Servs.*, 104 Fed. Cl. 457, 467 (2012).

The Vaccine Act was originally adopted by Congress to "establish a [f]ederal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3 (2d Sess. 1986), *reprinted in* 1986 U.S.C.C.A.N. 6334, 6334. Congress established a Vaccine Injury Table to allow for a generous remedial program.<sup>9</sup> For cases falling within the timing and other specifications of a Table injury, causation is conclusively presumed. *Hodges v. Secretary of Health & Human*

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<sup>9</sup>The original Vaccine Injury Table was published at 42 U.S.C. § 300aa-14(a). The Secretary of Health and Human Services has periodically revised the Table pursuant to notice-and-comment rulemaking under the authority of 42 U.S.C. § 300aa-14(c), and the current version of the Vaccine Injury Table, as amended, is set out at 42 C.F.R. § 100.3.

*Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). For claims falling outside the scope of the Table, however, the claimant is required to prove causation in fact by a preponderance of the evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), -13(a)(1)(A); *Althen*, 418 F.3d at 1278.

Causation in fact is proved by a petitioner who satisfies each of three *Althen* factors by preponderant evidence. *Althen*, 418 F.3d at 1278 (quoted *supra*, at 6). Expanding on these criteria for establishing causation, the Federal Circuit stated that “[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the logical sequence being supported by reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Id.* (citation omitted) (internal quotations omitted). Once the petitioner has made a prima facie case of causation, “the burden shifts to the government to prove by a preponderance of the evidence that the petitioner’s injury is due to factors unrelated to the administration of the vaccine . . . .” *de Bazan v. Secretary of Health & Human Servs.*, 539 F.3d 1347, 1352 (citation omitted) (internal quotation omitted).

The Federal Circuit has interpreted the “preponderance of the evidence” standard for Vaccine Act cases as the same as the standard used in traditional tort cases, *see Moberly ex rel. Moberly v. Secretary of Health & Human Servs.*, 592 F.3d 1315 (Fed. Cir. 2010), requiring the claimant to establish “more probable than not” causation, *Althen*, 418 F.3d at 1279 (citation omitted). “[C]lose calls regarding causation are resolved in favor of injured claimants.” *Andreu*, 569 F.3d at 1378 (quoting *Capizzano*, 440 F.3d at 1325-26). The preponderance standard employed by the Vaccine Act “allow[s] the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body,” *Althen*, 418 F.3d at 1280. Thus, proof by a preponderance of the evidence does not require “scientific certainty.” *Bunting v. Secretary of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). Rather, determination of causation under the Act involves “ascertaining whether a sequence of cause and effect is ‘logical’ and legally probable, not medically or scientifically certain.” *Knudsen ex rel. Knudsen v. Secretary of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994) (citations omitted). Therefore, a finding of causation in fact in vaccine cases can be “based on epidemiological evidence and the clinical picture . . . without detailed medical and scientific exposition on the biological mechanisms.” *Id.* at 549 (citing *Jay v. Secretary of the Dep’t of Health & Human Servs.*, 998 F.2d 979, 984 (Fed. Cir. 1993)).

While a special master may base his or her decision on medical opinion alone, *Althen*, 418 F.3d at 1279-80, he or she is “entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly*, 592 F.3d at 1324 (citing *Terran v. Secretary of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). In addition, the special master may also consider medical literature or epidemiological evidence in reaching an informed judgment as to whether a particular vaccination caused a particular injury. *See LaLonde v. Secretary of Health & Human Servs.*, 746 F.3d 1334, 1339-40 (Fed. Cir. 2014).

## ANALYSIS

Based on the lack of a formal diagnosis for J.H.’s severe neurological impairment, it is undisputed that petitioners’ claim involves an “off-Table” condition, *i.e.* an injury not listed in the Vaccine Injury Table delineated in 42 U.S.C. § 300aa-14(a). *See* 42 U.S.C. § 300aa-



11(c)(1)(C)(ii). Accordingly, petitioners bear the burden of proving causation in fact by a preponderance of the evidence. Based upon the record, four separate possible theories of J.H.'s condition have been or may be posited:

1. **Challenge/Rechallenge Scenario:** J.H. was healthy until she received the October 2004 injection; she had adverse reaction then; in November 2004 she received a second dose; and her condition soon became drastically worse.
2. **All Other Possible Causes Have Been Eliminated:** J.H.'s condition (according to medical experts) must have been prompted by a trigger; extensive testing has eliminated all other potential causes of her condition, leaving only the influenza vaccinations, implicating a theory akin to *res ipsa loquitur*.
3. **Exacerbation of Underlying Condition:** J.H. suffered from an underlying immunological condition prior to October 2004, but the half-doses of the influenza vaccination caused her condition to develop into a severe neurological impairment.
4. **Other Vaccination Received in July 2004 was Cause:** Plaintiff's expert Dr. Oleske, admitted that J.H.'s receipt of other vaccines in July 2004 was a possible cause of J.H.'s impaired condition, but claimed this possibility was mere "speculation" because it could not be proven.

Conceptually, possibilities 1, 2, and 4 fit within the *Althen* causation principles, while possibility 3 would require consideration of the *Loving* significant-exacerbation factors.

#### **A. Causation Under *Althen* Factors**

The special master's denial of the petitioners' petition rested largely on evidence suggesting that J.H.'s neurological degeneration predated her receipt of the two half-doses of the influenza vaccine on October 14, 2004 and November 16, 2004, respectively. The second special master found Dr. McGready's testimony to this effect more persuasive than the contrary view of Dr. Oleske, which the second special master concluded suffered from several deficiencies. Entitlement Decision at 10. Most importantly, the special master noted that Dr. Oleske based his opinion on a "plainly flawed" assumption regarding the onset of J.H.'s neurological symptoms. *Id.* at 10-11. While Dr. Oleske concluded that J.H.'s symptoms did not begin until after her first influenza vaccination on October 14, 2004, the special master observed that this testimony was refuted by both the findings of the original special master after the 2008 onset hearing and J.H.'s medical records.

The special master's conclusion regarding the onset of J.H.'s symptoms is supported by both the facts and the record. J.H.'s medical records document a change in J.H.'s circumstances between her six-month visit with Dr. Peera in July of 2004 and her nine-month visit on October 14, 2004. Entitlement Decision at 11. At six months of age J.H. was able to roll over in both directions, reach for objects, babble, and appeared normal for her age. At nine months, however, J.H. was no longer rolling over or sitting alone and had decreased muscle tone in her lower

extremities. *Id.* The testimony of J.H.'s parents similarly supports that the onset of J.H.'s condition occurred prior to October of 2004. In several different medical histories, J.H.'s parents noted that her development began to fall behind that of her twin brother at about six months of age, in July 2004. *Id.* at 12. Finally, the records of J.H.'s visit to the Mayo Clinic identify July to September of 2004 as the period of the first symptoms of her neurological deterioration. *Id.* The original special master at the onset hearing weighed the testimony of J.H.'s parents with that of her medical records. *Id.* He noted that while he found J.H.'s parents to be "credible" and "moral" people, he believed that the medical records as a whole indicated that J.H.'s neurological development was deficient in July of 2004. 2010 Tr. at 10.

Petitioners argue that the second special master ignored a significant portion of the record in rendering his decision. Specifically, they emphasize that the original special master stated that J.H.'s condition was a "form of retrogression" which initiated before October 14th, 2004. In this first special master's view, J.H.'s condition "seem[ed] to deteriorate, or accelerate, rapidly between October 14 and November [16th] and thereafter," demonstrating an "acceleration or degeneration of whatever the problem is." 2010 Tr. at 15. They contend that the second special master's lack of acknowledgment of the first special master's statements about acceleration, coupled with other probative evidence, including dated photographs of J.H.'s worsening condition over time, amounted to impermissibly "don[ning] blinders to the portion of [an evidentiary] letter that contradicted his findings." Pet'rs' Mot. at 15 (quoting *Shapiro v. Secretary of Health and Human Services*, 105 Fed. Cl. 353, 357 (2012), *aff'd*, 503 Fed. Appx. 952 (Fed. Cir. 2013)). Contrary to petitioners' contention, however, there is no indication in the second special master's thorough opinion that he failed to consider the evidence petitioners cite. In the opinion, the second special master explained that he reviewed the findings of the first special master and also conducted a detailed review of both the testimony of J.H.'s parents and notations in J.H.'s medical records. Entitlement Decision at 12. Furthermore, the first special master's bench ruling does not conflict with the second special master's decision. The first special master deliberately refrained from drawing any medical conclusions in his ruling. He neither identified a cause for J.H.'s neurological nose-dive nor suggested that the influenza vaccination itself aggravated her condition; he merely identified a time – a period undisputed by the parties – during which J.H.'s symptoms worsened significantly. The second special master accepted that J.H. experienced a dramatic neurological decline in the period after October 14th, but concluded through his analysis of the *Althen* factors that the evidence did not demonstrate that the decline was caused by J.H.'s vaccinations. *Id.* at 19-20.

In addition, the second special master undertook an overall review of petitioners' various theories of causation. First, he addressed petitioners' theory that an unusual immunological response to the influenza vaccine contributed to J.H.'s neurological disorder. Entitlement Decision at 13-15. His rejection of this theory was based on the absence of any medical literature or any plausible explanation by Dr. Oleske indicating that the influenza vaccine was capable of causing an unusual immunological response that could lead to a severe neurological decline. *Id.* In that respect, Dr. McGeady explained that nothing in J.H.'s records indicated that J.H. was immunologically abnormal or unusually susceptible to infections. *Id.* Petitioners dispute Dr. McGeady's conclusion that J.H. was immunologically normal after the flu vaccinations, relying primarily on results from tests at the Mayo Clinic in 2005. *See* Hr'g Tr. 22:16 to 23:1 (Nov. 13, 2014) ("We have the flu vaccination coming in, we have the theory that

it could be an autoimmune reaction, and we have the evidence from the Mayo Clinic and from Children’s Hospital of evidence of an immune response in her central nervous system. So, we know there’s an auto — there’s a possibility of an autoimmune reaction. We have symptoms of it. We have fingerprints of it in the tests. They are slight fingerprints, but they are fingerprints. And then we have the work of Children’s Hospital excluding everything else.”). To further support the theory of an autoimmune reaction, petitioners point to two autoimmune conditions, Guillain-Barré syndrome and Chronic Inflammatory Demyelinating Polyneuropathy, both of which are known to be caused by flu vaccines. Pet’rs’ Mot. at 8 (citing Dr. Oleske’s testimony, Ex. 17 at 3-4).<sup>10</sup> The special master discounted those conditions as providing any analogy to J.H.’s condition, commenting that “Dr. Oleske failed to point to any medical articles or other actual evidence demonstrating that influenza inoculations can injure the brain.” Entitlement Decision at 13.

Second, the special master’s rejection of petitioners’ “challenge/rechallenge” theory of causation was supported by the fact that J.H. suffered the first symptoms of her neurological disorder *before* her first influenza vaccination, which is inconsistent with a “challenge/re-challenge” scenario. *Id.* at 15.<sup>11</sup> Although the special master’s decision did not appear to address in this context the significant worsening of J.H.’s condition in late 2004 and early 2005, those changes did not follow immediately after the half-dose influenza vaccinations.

### **B. Signification Aggravation Theory**

During the hearing held on November 13, 2014, petitioners moved to amend their petition for compensation to incorporate a significant-aggravation claim, arguing that an autoimmune reaction to the flu vaccine may have exacerbated an underlying condition, resulting in J.H.’s neurological decline. Hr’g Tr. 52:11-14, 50:14-19 (Nov. 13, 2014) (“[I]f the pleadings don’t cover the aggravation, I move to amend the pleadings to conform that proof, as we do all the time in court when things turn out differently.”). In support of their theory, petitioners cite results from the Mayo Clinic and Children’s Hospital suggestive of an autoimmune reaction and the general timing of J.H.’s accelerated neurological decline, which followed her receipt of the vaccines. Hr’g Tr. 22:16 to 23:19 (Nov. 13, 2014). The government counters that a significant-aggravation claim was never fully developed in the pleadings or by petitioners’ expert. Hr’g Tr. 39:11-21 (Nov. 13, 2014).

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<sup>10</sup>Guillain-Barré syndrome is a disorder in which the body’s immune system attacks part of the peripheral nervous system. Chronic Inflammatory Demyelinating Polyneuropathy is a neurological disorder characterized by progressive weakness and impaired sensory function in the arms and legs. This condition is often considered the chronic counterpart to the acute Guillain-Barré syndrome.

<sup>11</sup>A “challenge/rechallenge” circumstance exists when a person has a reaction to one administration of a vaccine or drug and then suffers worsened symptoms after an additional administration of the same vaccine or drug. Entitlement Decision at 15. A challenge/rechallenge theory can be used to establish causation. *Id.* (citing *Capizzano v. Secretary of Health & Human Servs.*, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Sp. Mstr. June 8, 2004), *aff’d*, 63 Fed. Cl. 227 (2004), *rev’d on other grounds*, 440 F.3d 1317 (Fed. Cir. 2006)).

Under Rule 15(b)(2) of the Rules of the Court of Federal Claims (“RCFC”), a party may move at any time to amend the pleadings to incorporate an issue that is tried by the parties’ express or implied consent.<sup>12</sup> The decision to grant such a motion rests in the sound discretion of the trial court. *See Grand Light & Supply Co. v. Honeywell, Inc.*, 771 F.2d 672, 680 (2d Cir. 1985) (citing *Browning Debenture Holders’ Comm. v. DASA Corp.*, 560 F.2d 1078, 1086 (2d Cir. 1977)).<sup>13</sup> The purpose of RCFC 15(b) is to enable the pleadings to conform to issues “actually tried, not to extend the pleadings to introduce issues inferentially suggested by incidental evidence in the record.” *Id.* (quoting *Browning Debenture*, 560 F.2d at 1086). The rule should also be applied in a manner that avoids unfair prejudice, which may occur where a party seeks to apply evidence presented on a separate issue to a new claim added after conclusion of the trial, *see id.* at 680 (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 330–31 (1971); *Cook v. City of Price*, 566 F.2d 699, 702 (10th Cir. 1977)), or if the opposing party did not have the opportunity to defend against the new claim and might have offered additional evidence had it been aware of the claim, *see id.* (citing *International Harvester Credit Corp. v. East Coast Truck*, 547 F.2d 888, 890 (5th Cir. 1977)).

In this instance, petitioners waited to raise a significant-aggravation claim until after a decision was rendered by the special master following the conclusion of percipient witness and expert testimony. While the evidence cited by petitioners that would support a significant-aggravation theory was submitted at the hearings before both special masters, it was submitted in support of separate and distinct theories of causation, *i.e.*, a challenge/rechallenge scenario and an immunological response causing neurological dysfunction beginning *after* the administration of the influenza vaccine. Therefore, the issue of significant aggravation is “inferentially suggested by incidental evidence” rather than “actually tried,” *Grand Light*, 771 F.2d at 680 (citation omitted), and there was no implied consent by the government to try the issue in the underlying proceedings, *see, e.g., Paul Revere Life Ins. Co.*, 354 F.3d 1005, 1013 (9th Cir. 2004) (noting that Fed. R. Civ. P. 15(b) “does not permit amendments to include issues which may be [merely] inferentially suggested by incidental evidence in record” (citations omitted)); *DRR, LLC v. Sears, Roebuck and Co.*, 171 F.R.D. 162, 165 (D. Del. 1997) (finding the issue was not tried by implied consent of parties when relevant evidence was introduced at trial only in support of original claim and the opposing party was not put on notice that the issue was being tried); *Metcalf Const. Co. v. United States*, 102 Fed. Cl. 334, 343 (2011) (noting “where evidence is introduced at trial to establish a properly pled issue, implied consent may not be assumed as to issues not pled”).

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<sup>12</sup>RCFC 15(b)(2) states in pertinent part:

When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings. A party may move--at any time, even after judgment--to amend the pleadings to conform them to the evidence and to raise an unpleaded issue. But failure to amend does not affect the result of the trial of that issue.

RCFC 15(b)(2).

<sup>13</sup>RCFC 15(b) mirrors Fed. R. Civ. P. 15(b). The court accordingly will look to precedents applying Fed. R. Civ. P. 15(b) in addition to those addressing RCFC 15(b).

Moreover, allowing the claim at this stage of the litigation, over eight years after the filing of the original petition for compensation in May 2006, would unfairly prejudice the government. *See Baker v. Goldman, Sachs & Co.*, \_\_ F.3d \_\_, \_\_, 2014 WL 5840501, at \*12 (1st Cir. Nov. 12, 2014) (noting that plaintiffs' general argument that the defendant's failure to disclose relevant facts about a transaction in violation of a specific statute was insufficient to put defendant on notice of a claim falling under a different statute); *Rodriguez v. Doral Mortg. Corp.*, 57 F.3d 1168, 1172 (1st Cir. 1995) (plaintiff may not "leave defendants to forage in forests of facts, searching at their peril for every legal theory that a court may some day find lurking in the penumbra of the record"). Notably, the legal test for significant-aggravation claims differs from that applicable to petitioners' other claims.<sup>14</sup> Importantly also, no testimony whatsoever has been presented on a significant-aggravation theory by an expert witness. Indeed, petitioners concede that a significant-aggravation theory would contradict the testimony of their own expert, Dr. Oleske, who testified that J.H. developed normally until October 14, 2014. Hr'g Tr. 51:15-17 (Nov. 13, 2014) ("Dr. Oleske still doesn't believe this child had a problem in the summertime. He and I disagree."). In these circumstances, the court declines to permit petitioners to amend their petition to incorporate a significant-aggravation claim at this stage of the proceedings.

### C. Synopsis

In sum, due to evidence that the onset of J.H.'s condition occurred prior to the administration of the two half-dose influenza vaccinations and the lack of evidence supporting the persuasiveness of petitioners' proffered medical theories, the court finds that the special master weighed the evidence of record and made determinations in accord with law. Applying the pertinent evidentiary standard, the court concludes that the special master's finding of a lack of causation was supported by substantial evidence and was neither arbitrary nor an abuse of discretion.

### CONCLUSION

For the reasons stated, petitioners' motion for review is DENIED, and the decision of the special master rendered on August 26, 2014 is AFFIRMED.

It is so **ORDERED**.

s/ Charles F. Lettow

Charles F. Lettow

Judge

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<sup>14</sup>The six-part *Loving* test that pertains to a significant-aggravation claim, *see Loving*, 86 Fed. Cl. 135, adds three factors to the causation criteria specified in *Althen*, *see supra*, at 2 n.2.